Chapter 12

Patents and Technology Transfer

This chapter covers the ARS guidelines set forth for reporting inventions; obtaining patents and Plant Variety Protection Certificates; licensing; and distribution of license income (including awards to inventors). Technology Transfer Agreements with ARS provide access to research information and assist in the development and commercialization of new knowledge and technology.

Acronyms: See Chapter 22 for a comprehensive list of commonly used acronyms.

References:
P&P 141.2 – Technology Transfer in ARS
P&P 324.0 – Reimbursable and Trust Fund Agreements
P&P 601.2 – Transfer of Biological Agents and Related Information to Non-USDA Locations and Individuals
NPA–PM 03-003 – Use of High Consequence Livestock Pathogens and Toxins, Listed Plant Pathogens and Select Agents and Toxins
NPA-PM 05-003 – Submission of ARS Plant Material Release Notices
Partnering – Technology Transfer Offices Brochure
Booklet – Patents in ARS, A Plain Language Guide

Cross References: Chapter 16 – Agricultural Research Information System (ARIS)

Web Sites:
Program Aid 1706: Forming Partnerships with the Agricultural Research Service
http://www.ars.usda.gov/is/np/formingpartnerships
USDA-ARS Partnering
www.ars.usda.gov/business

Attachment 1: Instrument Selection
Attachment 2: CRADA Review Procedures
Attachment 3: ARIS Instructions Plant Material Docket 03-04-10
Attachment 4: ARIS Template Plant Material Docket
Attachment 5: ARIS Example Disclosure
Attachment 6: ARIS Example Invention

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TECHNOLOGY TRANSFER IN ARS

The role of a government scientist has experienced a significant change in the past decade. Historically, expectations were often limited to publication and the exchange of technical information among peers. With the advent of the Technology Transfer Act in the mid 1980's, the goals of federal research programs began a fundamental shift toward the development of tangible benefit for the public.

In this new environment, emphasis has now been placed upon the scientist to create interactive relationships with corporate counterparts, where their research supports such. The thinking is that in many cases the public will not directly (and measurably) benefit from federal research without an industrial champion who will carry the beginning technology through the stages of refinement and marketing, for which the federal lab is both ill-equipped and does not possess an accepted mandate.

IMPACT

At the agency level the goals of technology transfer manifest themselves to the scientist in the form of the RPES, wherein it is requisite that the researchers show the "impact" of their work. Several "tools of the trade" in the technology transfer process are useful in substantiating this "impact" for the scientist. These include patents, licenses, and Cooperative Research and Development Agreements (CRADA's).

Through the experience of the last several years, it has been found that pickup of Agency developments by the corporate sector is critical in order to bring about maximal public use and benefit.

PATENT PROCESSING PROCEDURES

Generally, it is ARS policy not to delay public release of research results because of patents. Instead, scientists are urged to notify Patent Advisors (PA's) of potentially patentable inventions and discoveries at the time they are recognized and preferably no later than when manuscripts are prepared for peer review. This generally allows time for the patent to be filed at the U.S. Patent and Trademark Office before the publication becomes (in patent parlance) a statutory bar.

Refer to "Patents in ARS, A Plain Language Guide," revised October 1997, for general information on patenting in ARS and Directive 141.2, "Technology Transfer in ARS," for important details.

The formal process begins with an Invention-Patent Docket Disclosure Report (IR) which is submitted electronically on the Agricultural Research Service Licenses/Inventions module in ARIS. The IR proceeds electronically through line management clearance procedures. Send an e-mail to the Area Extramural Agreements Specialist for alert to process file in ARIS Licenses/Inventions.

The IR should be submitted as early in the research progress as possible, preferably no later than when a formal scientific manuscript reporting the relevant research has been prepared. The requirement remains that prior to submitting the manuscript to a journal an ARS-115 must be entered into ARIS with the appropriate patent coding as well as the IR.

It is important to remember that as a separate act, a hard copy of the IR must be printed, signed and dated by inventor(s), witnessed (signed and dated), and forwarded immediately to your Area Patent Advisor (PA), address on front page.

Inventors are encouraged to conduct a literature search including both domestic and foreign patents before preparing the IR and, if possible, forward it to the PA with a statement as to how the invention is different from the most relevant known technology and that technology found during the search.

PATENT CLEARANCE PROCEDURES

The Agency decision process with regard to patents is as follows:

1. Scientists should notify their RL, Technology Transfer Coordinator (TTC), and PA as soon as possible after they achieve what they believe to be a patentable invention. While domestic rights are available for one year after a scientist's own disclosing publication, foreign rights for the same invention are less instantaneously with disclosure, whether oral or written.

2. If the RL, TTC, and PA agree that a patentable invention may have been achieved, the PA will request a formal IR and such other written documentation as may be appropriate. The IR, upon entry in ARIS, is electronically forwarded through the Research Leader and Center Director to the PA.

3. If after reviewing the information provided, the PA still believes the research achievement may be patentable, the PA will put it on the agenda for the next appropriate Patent Committee (PC) meeting. In urgent cases, the PA may distribute the information immediately to the members of the PC and then poll them by telephone for a recommendation. Another alternative is to request that one of the other Patent Committees meeting earlier be asked to handle the urgent case. The PA will place each case in one of three categories: APPROVED (recommended for filing a patent application); DEFERRED (to be held until one or more deficiencies are met); or SUSPENDED (recommended for publication in lieu of patenting).

4. After the PC meeting or polling by telephone, the PA will place inventions recommended for patents on the IR docket and send the Area Director (AD) and Inventor(s) a report of the PC's recommendations and each IR under the AD's jurisdiction.

5. No action is required by an AD who agrees with the recommendations of the PC. If the AD disagrees with any of the recommendations, the AD should contact the Assistant Administrator, OTT (name and address on front). Additional information will be requested, as needed, e.g., from the appropriate NPS members, to make a final decision.

6. When a PA sends a completed patent application forward to the USDA patent attorney for filing in the U.S. Patent and Trademark Office, a copy of the transmittal memo should be sent to the AD of each inventor. After a serial number is assigned to the application (usually 6-8 weeks later), a copy of the application will be forwarded to the AD.

PENDING CASES FOR PATENT COMMITTEE MEETING

Patent Committee meetings are now scheduled on approximately a quarterly basis, with one meeting a year done in person and the others handled through telephonic conferencing. Cases needing speedy review may be transferred to another committee or handled on an ad hoc basis.

The following criteria are used by the Patent Committees in assisting PA in evaluating invention reports:

1. Is there current commercial interest in the invention or a high probability of commercialization in the future?

2. Is the magnitude of the market relative to the costs of commercialization large enough to warrant a patent?

3. Would the patent likely play a significant role in transferring the technology to the user beyond what could be achieved through publication?

4. Would a patent on this invention be enforceable, i.e., is the invention drawn to, or does it employ, a unique and readily identifiable material or device which could be bought or sold?

5. Is the invention of sufficient scope to justify patenting?

PATENT LICENSING

ARS no longer favors royalty-free license arrangements. Only those ARS patents licensed previously as domestic, non-exclusive royalty-free and where the licensee is active will be maintained as such until the patent expires or the license is terminated. It has been proven that inventions made available freely to all have been used by only a few.

As a general policy, all patents will be licensed on a fee-bearing basis with some form of an incentive to exclusivity to assure product availability to the public. Patents involving technologies where the industry investment is minimal are sometimes considered on a non-exclusive basis.

ARS inventors will be contacted as a source of expertise by the Agency licensing team when patents are being considered for licensing. Inventors, however, are not allowed to participate in the negotiation process to avoid conflict of interest issues.

License application forms are maintained and distributed to industry by the License Coordinator and Technology Transfer Coordinators. ARS strives to negotiate fair licensing terms and conditions, considering both the interest of the U.S. Government in promoting commercialization of Federal research results and the need to provide a proper reward to the inventor(s)

PATENT LICENSE AWARDS

ARS Inventors of a given invention collectively receive the first $2,000 of any licensing fee and 25 percent of the Agency's share of license income up to a maximum of $150,000 per inventor per year. In situations with multiple inventors, the income is shared equally.

CONFIDENTIALITY AGREEMENTS

http://www.ars.usda.gov/business/docs.htm?docid=771&page=3

It is important for the scientist to realize that a potential cooperator needs to be given sufficient information so that they can make an informed decision as to whether or not a particular technology is for them. The Confidentiality Agreement, in addition to protecting potential patent rights, should give the scientist a measure of comfort in knowing that by sharing early information, others won't run off with it and either misrepresent it or claim it as their own. The Confidentiality Agreement does not however create an obligation for the scientist to "tell all." Sometimes being "coy" with critical details is desirable - they may not be necessary for a sound business decision and, if the arrangement breaks down, it is preferable that the party not know enough so as to successfully engineer around our technology.

Copies of the agreement may be obtained from your TTC. The TTC will prepare the agreement and send it to the scientist for signature. Any full time scientist or engineer may sign this agreement. If a company provides an ARS scientist or engineer with the company's confidentiality agreement, it must be reviewed and approved by the Area Technology Transfer Office before it is signed.

MATERIAL TRANSFER AGREEMENTS (MTA)

http://www.ars.usda.gov/business/docs.htm?docid=771&page=2

In some situations, the exchange of information may include the transfer of material from one party to the other. For these instances, another form of document has been created - the Material Transfer Agreement. This document states that whatever materials that are transferred must be destroyed and/or returned upon completion of their testing and that no commercial usage may be made of them without permission by the Agency. There are special restrictions regarding the transfer of pathogenic organisms to non-USDA institutions. Contact your TTC to obtain a MTA.

Agricultural Research Service (ARS) employees frequently receive or send research materials to universities or private companies in the course of their work. Usually requests are made by research scientists, but requests may also involve technical and administrative support personnel. If the

materials are patented or could be at some future date, the sender will often require that the recipient sign an acceptance statement, sometimes called a Material Transfer Agreement (MTA).

Many institutions, both private and public sector, use Material Transfer Agreements to limit use of the material to the specific research at hand and also claim ownership of improvements made during the research. One purpose of a MTA is to convey to the recipient of the materials that, if the material is patented, a license will be needed for commercial development of the technology. The difficulty encountered in exchanging materials between university scientists is described in Science Vol. 278, page 212, 10 October 1997.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

http://www.ars.usda.gov/business/docs.htm?docid=771

Directive 141.2 "Technology Transfer in ARS" furnishes policy guidelines and a sample agreement. These multi-page agreements are too lengthy to be included here, but copies may be obtained by calling the Area Technology Transfer Office.

AGRICULTURAL RESEARCH SERVICE

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT REVIEW PROCEDURES

Cooperative Research and Development Agreements (CRADAs) have provided a valuable mechanism to form partnerships with private sector organizations. This authority has allowed the rapid development and transfer of many Agricultural Research Service (ARS) discoveries to solve critical problems. The success of this program has also led to an examination of the procedures used to review and approve a CRADA and to assure that the public mission of ARS research is not altered through the partnership.

This document describes the current review procedure that is given to each CRADA before approval by ARS. Also, an additional review procedure is described to allow early identification of research areas requiring specific agency policy review. The roles of the ARS Office of Technology Transfer (OTT), National Program Staff (NPS), Area Directors (AD), and other line managers are described.

CRADA Review Procedures: The current ARS CRADA review and approval process involves NPS, AD, line management, and OTT. The ARS scientist and OTT Technology Transfer Coordinator (TTC) discuss the CRADA requirements and the proposed plan of research with the potential cooperator. The Unit Research Leader and or scientist, other line managers, and the NPS are first consulted to assure that the collaboration is appropriate to the approved research program and that sufficient resources are available to complete the planned research. This process occurs prior to entry of the incoming agreement into ARIS for CRADA project line management approval. CRADAs may or may not have incoming funds, but both partners must actively participate in the research. In addition to intellectual input and proprietary information, such participation may involve contributions of personnel, equipment, supplies, materials, facilities, etc. CRADAs cannot be used simply as a means to bring in outside funds, nor should they be used to test, develop, or validate a company's product. CRADAs are appropriate vehicles for 1) transfer and/or further development of ARS technology, 2) collaboration using the cooperator's intellectual property, or 3) merging of ARS discoveries with the cooperator's technology. CRADAs are developed by scientists and TTCs, approved by NPS, the AD, and line managers, and signed by OTT on behalf of ARS. Each CRADA also has documented approval by the incoming agreement project clearance procedures.

INFORMATION REQUIRED FOR REVIEW OF A CRADA:

A. Title, Laboratory, Lead Scientists, Location, Proposed Cooperator.

B. Summary of Proposed Research: A brief description describing the problem, research objectives, methods, etc.

C. Criteria to be considered when evaluating a CRADA:

1. How does the proposed research further the ARS mission?
2. What technology, expertise, financial resources, etc., would be contributed by the cooperator?
3. What are the possible end products of the research?
4. How will the end products be used?